4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0918]

Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling Requirements for Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with labeling requirements for prescription drugs.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include Docket No. FDA-2021-N-0918 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling Requirements for Prescription Drugs and Biological Products." Received comments, those filed

in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Labeling Requirements for Prescription Drugs

OMB Control Number 0910-0572--Revision

This information collection supports FDA regulations governing the labeling of prescription drugs. The regulations are codified in 21 CFR part 201, subpart B (21 CFR 201.50 through 201.58) and set forth both general requirements, as well as specific content and format

requirements. The regulations also provide for requesting a waiver from any labeling requirement and do not apply to biological products that are subject to the requirements of section 351 of the Public Health Service Act.

We are revising the information collection to include burden associated with regulations applicable to medical gas labeling found in § 201.328 (21 CFR 201.328) and established by a final rule in the *Federal Register* of November 18, 2016 (81 FR 81685 at 81694). While we included corresponding changes and adjustments resulting from the final rule to the information collection approved under OMB control number 0910-0139 as it pertains to good manufacturing practice requirements and regulations in part 211 (21 CFR part 211), we did not make corresponding changes and adjustments to this information collection with regard to burden that may be associated with labeling requirements found in § 201.328 (81 FR 81685 at 81694).

To assist respondents with the information collection we continue to develop and issue guidance documents, available from our searchable guidance database at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. All Agency guidance documents are issued consistent with our good guidance practice regulations found in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Labeling requirements for prescription drugs; §§ 201.56 and 201.57	414	1.326	549	3,349	1,838,601
Labeling of medical gas containers; § 201.328	260	1,663	432,380	0.17 (10 minutes)	43,238
Total			432,929		1,881,839

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

New drug product and biological product applicants must: (1) design and create prescription drug labeling containing “Highlights,” “Contents,” and “Full Prescribing Information”; (2) test the designed labeling (for example, to ensure that the designed labeling fits

into carton-enclosed products); and (3) submit it to FDA for approval. Based on our experience with the information collection, we estimate 414 applicants will prepare an average of 549 prescription drug labels and assume it will require 3,349 hours to design, test, and submit to FDA as part of a new drug application or a biologics license application. Similarly, new medical gas containers must meet applicable requirements found in part 211, as well as specific labeling requirements in § 201.328. We estimate that 260 respondents will incur burden for the design, testing, production, and submission of labeling for new medical gas containers as required under § 201.328 and assume an average of 10 minutes (0.17) is required for these activities.

Our estimated burden for the information collection reflects an overall increase resulting from an increase in submissions for new product labeling as well as from the revision to include burden associated with requirements in § 201.328.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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